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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,002	05/20/2005	Ugur Sahin	4883-0001	7473

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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

NOTIFICATION DATE	DELIVERY MODE
11/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com
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Advisory Action Before the Filing of an Appeal Brief	Application No. 10/537,002	Applicant(s) SAHIN ET AL.	
	Examiner Peter J. Reddig	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *99-104 and 116-121*.
   Claim(s) withdrawn from consideration: *107-115*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Continuation of 3 and 11. NOTE: Continuation of 3 and 11. NOTE: The newly aded claims and limitations are drawn to issuses that require new considerations and search as the amended claims are now additionally drawn to pancreatic and esophageal cancer.

If the amendment were to be entered, Claims 99-104 would remain and new claims 116-121 would be rejected under 35 USC112, first paragaph, for the reasons previously set forth in the Office Action of June 27, 2007, section 5, pages 3-4.

Applicants argue that claims 99-101 have been amended to disclose a methodology of diagnosing stomach, lung, and pancreatic cancers. Applicants argue that the Examiner's rejection has been rendered moot. Applicants argue that the diagnosis of pancreatic cancer is also enabled in the instant specification. (See Example 4, pages 67-70 of the translated priority document (German Application No. 102 54 601.0); and Example 4, pages 92-99 of the instant specification.) Additionally, the Applicants argue that the diagnosis of esophageal cancer is also enabled in the instant specification. (See Table 3A of the instant application, page 94.) Independent claim 99 has been amended to recite a method of diagnosing stomach, lung, and pancreatic cancers. Independent claim 116 recites a method of diagnosing esophageal cancer. Applicants argue that the instant specification, specifically Example 4, provides a complete description so that a skilled artisan can make and use the claimed invention.

Applicants' arguments have been carefully considered, but have not been found persuasive because the amendment has not been entered and will not be entered for the reasons set forth above, thereforethe claims have not been amended and the rejections remain for the reasons previously set forth. If the amendment were to have been entered, Applicants' arguments would have not been found persuasive because the German Application No. 102 54 601.0 does not provide enabling support for diagnosing a pancreatic cancer by detecting SEQ ID NO: 16 (claudin 18A2.1) because 102 54 601.0 only teaches detecting claudin 18A2.1 mRNA in tumors (see Example 4, p. 67-70, Table 3 and Fig. 5). Additionally, Table 3 of German Application No. 102 54 601.0 shows the level of expression of 18A2.1 mRNA to be the same in pancreatic cancers and normal pancreatic tissue. Thus, even if it were found that mRNA levels correlated with protein levels, one of skill in the art would not predictably expect to diagnose pancreatic cancer based on the level of SEQ ID NO: 16 (claudin 18A2.1) given that they appear to have the same level of expression. Additionally, Example 4, pages 92-99 and Table 3 of the instanst specification are drawn only to mRNA expression in the pancreas and espophogeal cancer, thus for the reasons previously set forth drawn to a lack of a predictable correlation between mRNA and protein levels, the rejection would be maintained.

If the amendment were to be entered, Claims 99-104 would remain rejected and new claims 116-121 would be rejected under 35 USC 112, first paragaph, for lacking an adequeate written description for the reasons previously set forth in the Office Action of June 27, 2007, section 6, pages 4-5.

Applicants argue that they have amended the claims for clarity. Specifically applicants have amended independent claim 99 which is now directed to detecting the expression of a tumor-associated antigen in a biological sample, where the tumor-associated antigen is either the polypeptide of SEQ ID NO:16 or a polypeptide encoded by a nucleic acid of SEQ ID NO:7.

Applicants' arguments have been carefully considered, but have not been found persuasive because the amendment has not been entered and will not be entered for the reasons set forth above, thereforethe claims have not been amended and the rejections remain for the reasons previously set forth. If the amendment were to have been entered, Applicants' arguments would have not been found persuasive because the claims are still drawn to a polypeptide of SEQ ID NO: 16 and a polypeptide encoded by a nucleic acid of SEQ ID NO: 7, all which read on fragments of the claimed polypeptides, and thus diagnosing cancer based on those fragments, thus the rejection for lacking an adequate written description would be maintained.

The priority data of the instant application remains May 20, 2005, for the reasons previously set forth in section 4, pages 2-3 of the Office Action of June 27, 2007.

Applicants argue that the priority application, German Application No. 102 54 601.0, sets forth that SEQ ID NO:16 encodes the claudin-18A2.1 translation product that "can be used as a marker to detect tumors of the upper gastrointestinal tract, in particular stomach carcinoma and pancreatic carcinoma." (See Example 4, page 67, lines 15-20.) There is sufficient support within this application to show a correlation of mRNA levels and the protein that is translated by said mRNA. (See Example 1, pages 59-62 and Example 4, pages 67-70.)

Applicants' arguments have been carefully considered, but have not been found persuasive because the disclosure of the prior-filed application, German Application No. 102 54 601.0, fails to provide adequate support or enablement because 102 54 601.0 only teaches detecting claudin 18A2.1 mRNA in tumors (see Example 4, p. 67-70, Table 3 and Fig. 5) and for the reasons set forth on pages 12-14 of the Office Action of October 17, 2006, the detection of mRNA does not predictably extrapolate to the detection of proteins. Additionally Example 1, pages 59-62, does not provide support for the instant claims as it is not drawn to claudin 18A.2.1/SEQ ID NO: 16.